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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,915	11/13/2001	Christine Nicol	2296.2320	7698
5514 7590 10/31/2007 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 and filed 8/21/2007. Claims 1, 2, 7-18, 20-25, 28-30 and 34 are pending. No claim is amended after the final rejection.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/21/07 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 7-18, 22, 23, 28-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998); all previously provided. The amendment of the claims to recite oral administration puts claims 20 and 21 in play and are thus included in the rejection because, since it is known in the prior art that carbonate antacid reduces stereotypy, it would be obvious to one of ordinary skill in the art at the time the invention was made to include the carbonate or Founderguard in the animals feed from birth or in the diet of lactating mother and expect that the baby animal fed the fortified food would grow up to an animal with a reduced tendency of stereotypy

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors. The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139). A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where Founderguard supplements the feed for treating stereotypic behavior in animals. Johnson and Winskill clearly teach the method of the instant claims except that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior and with the expectation that the histamine type-2

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antagonists or proton pump inhibitor will reduce or inhibit gastric secretion leading to treatment of stereotypy or cribbing.

5. Claims 24 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

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A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Winskill, Pagan and Johnson. One having ordinary skill in the art would have been motivated to include the antacid of Johnson or Pagan in the feed of Winskill as feed for horses and the modified composition would be expected to reduce hindgut acidity or control the pH of the hindgut and thus minimize the incidence of stereotypy in horses.

Remarks:

No further arguments is made with the filing of the RCE. The arguments presented after the final rejection were addressed in the advisory action of 7/16/07 and is reproduced below:

Response to Arguments

6. Applicant's arguments filed 6/25/07 were fully considered in the advisory action of 7/16/07 and were not persuasive. The response given in the advisory action is reproduced herein:

Amendment to the claims reciting oral did not overcome the rejection as stated in the office action of 12/21/06 because the composition containing sodium carbonate is fed to horses by oral feed and it is not as applicant puts it "orally feed sodium carbonate to horses." Applicant acknowledges that in the introduction, Johnson talks about administering sodium carbonate to horses by way of the caecum," however, specifically, Johnson refers to the effect of the

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carbonate on acidity of the hindgut and stereotypy so that it would be obvious to include carbonate in the feed of horses in order to treat acidity and stereotypy of the horses; b) Willard was not cited as art and the reliance on Johnson is the teaching that carbonate lowers incidence of stereotypic behavior, Johnson recognizes the relationship of acidity and stereotypy and specifically notes that lowering of acidity leads to reduction in stereotypy. Thus, it flows that reduction in the acidity of the intestinal tract would lead to reduction in stereotypy; c) It is further noted that claim 1 is not a method claim but a composition claim and the recitation of "for use or amelioration of animal stereotypy ..." is an intended use of the composition or the effect of that composition once administered; d) Regarding the Pagan reference, it is noted that, Pagan specifically associates gastric acidity with ulcers and uses the histamine type-2-antagonists and proton pump inhibitors to treat the ulcer or emanating from gastric acidity. It was noted in the final rejection of 12/21/06 that the stomach, the caecum and the hindgut are all part of the equine digestive system. e) it is known in the art that gastric acidity is associated with equine stereotypy, as is evidenced in Johnson, such that treating gastric acidity would invariably treat stereotypy in the equine. f) the new ground of rejection is the inclusion of claims 20 and 21, with claims 1, 2, 7-18, 22, 23, 28-30 and 34 as being unpatentable over Winskill in view of John and further in view of Pagan. The 1.132 declarations filed 10/11/06 was not effective to overcome the rejections on record as was described in the Office action of 12/21/06.

Remarks regarding Interview request: In the paper filed 8/21/07, applicant indicated that attorney would be contacting the examiner "within the next few weeks to

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schedule the interview.” However, the examiner has not been so contacted. Examiner is willing to conduct an interview with the attorney when one is so requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "MB Fubara", is written over the printed name of the examiner.